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(71) Applicant
(for all contract states outside US)
CREATETECHNIC AG. [CH/CH]
Hakabstrasse 5 CH-8309
Nürensdorf, (CH)

(72) Inventor; and

(75) Inventor and Applicant *(only for US)*
Dubach, Werner, Fritz [CH/CH]
Im Hubrain 4 CH-8124 Maur (CH)

(74) Patent attorney:
Patentanwaltsbüro Feldmann, AG
Kanalstrasse 17
CH-8152 Glattbrugg (CH)

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Published
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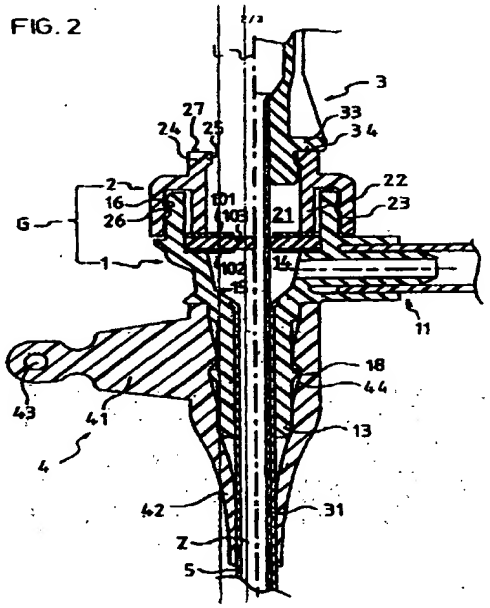
With changed Claims.

(54) **Title: Instruments for introducing catheters**

(57) **Summary:**

The invention relates to instruments for introducing catheters, comprising a hemostatic valve, used for introducing a catheter into a blood vessel. The hemostatic valve is accommodated in a two part housing (1, 2). Between the two parts of the instruments' housing (1, 2) is at least one sealing element (10) having a positive and/or a non-positive fit, designed to allow elongated component parts to be passed through in a sealing manner. The invention is characterized, in that the sealing element (10) consists of at least one sealing washer (103) made of a soft, elastic foam plastic.

FIG. 2



Based on the letter codes for the identification of PCT-Contract states, the pertinent states for this application are identified below:

JP = Japan
US = United States

AT = Austria
BE = Belgium
CH = Switzerland
DE = Germany
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NL = Holland
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SE = Sweden

PCT/CH98/00001 WO 98/32484

Instruments for Introducing Catheters

Description

The present invention concerns an instrument for introducing catheters into a blood vessel in accord with the generic concept of Claim 1 wherein said instrument possesses a hemostatic valve for passage of a catheter

Catheter introduction devices are used for the repeated, simple and rapid insertion of catheters and other elongated rod shaped objects into large blood vessels.

Following a percutaneous puncture of the vessel, for example, by the Seldinger Method, the proximal area of an operational sheath, controlled by a guide wire, is led into the lumen of the vessel. This tube shaped hollow body does not bring about a temporary entry to the vessel, but presents a communicative connection with the fluid system of the body which fluid is under pressure. On this account, blood outflow on the distal end of the said operational sheath is prevented. At that point is normally placed a valve housing, which, by means of a valve apparatus, seals off the flow channel formed by the operational sheath to the outside. This valve apparatus must make possible the entry of catheters and other elongated, surgical instruments of various diameters into the operational sheath, and also aid the subsequent movements of the same, without allowing fluid to pass the valve apparatus.

Likewise, during and after the removal of the catheter, a liquid-tight shutoff must be assured of the channeling formed by the operational sheath. Upon the entry, removal or movement of the foreign object inserted, infiltration of air must be avoided, since otherwise, air bubbles can build up in the blood vessel, which can lead to life threatening embolisms.

State of the technology

EP 0 067 007 (Argon Medical Corp.) and EP 0 157 906 (E. Weck, Inc.) describe a hemostatic valve, which is constructed from a disk-like sealing means, with a central opening and a thimble shaped, slit diaphragm of natural or synthetic rubber, supported by a lateral fin.

EP 0 198 962 (Terumo) discloses a valve of a surgical apparatus, the two diaphragms of which are made from an elastomer such as natural or synthetic rubber. The disk shaped diaphragms are, respectively, provided with cross-over slits on both sides, which, however, do not penetrate the disks through their full thickness.

EP 0 308 815 (Cordis, Corp.) brings into public knowledge a separation valve comprising an elastomer separation element, which exhibits a plurality of radially positioned slits, which penetrate the separation element in helical fashion. The separation element is composed of silicon rubber with a Shore A hardness of 30 to 50 and with a portion of 2 to 10 wt% free silicone as a lubricant.

EP 0 316 096 (Diag, Corp.) proposes a one piece hemostatic valve sealing means, which possesses a sealing throat as well as sealing lips and is composed again of silicone rubber or latex.

EP 0 369 314 *[owner not named]* describes a hemostatic valve which exhibits valve disks having a plurality of superimposed slits, which disks are perforated as well and all being composed of latex or silicone rubber.

EP 0 370 720 and EP 0 370 721 (both of Terumo) make known one piece hemostatic valve bodies of natural or synthetic rubber, which possess at least two superimposed layers which in turn have elements which are slitted or perforated and further are in cylindrical or dome shapes.

EP 0 416 467 (Terumo) describes a surgical valve, which consists of a single disk of natural or synthetic rubber and has two mutually crossing slots. In this arrangement, each slot exhibits a differing width of opening on the two sides of the sealing disk. The opening breadth of the slots on one side are respectively different.

EP 0 513 969 (Diag. Corp.) is a development of a hemostatic valve based on EP 0 316 096 (Diag. Corp.) which, again, is made of natural or synthetic rubber.

EP0649 317 (Unisurge, Inc.) describes a one-piece valve construction for an introductory instrument made of elastomer material, which comprises a cylindrical wall and an upper wall placed perpendicular thereto plus a central opening and a lower, projecting, radially slitted wall. The valve construction is of silicone rubber of a Shore A hardness of 40 to 70.

EP 0 692 278 proposes a hemostatic valve in which is to be found a diaphragm of silicone rubber, the Shore A hardness of which is between 20 and 50. The elastomer material, from which the diaphragm is made, is treated with additives, which are said to increase the ease of sliding.

Comment on the conventional hemostatic valves

All of these valve designs attempt to fulfill the demands for a well functioning hemostatic valve, in that they employ valves which are made from elastomers. Such cross-linked, macromolecular raw materials are indeed quite capable os stretching, but give little reaction to compression. The valves known up to this time must, on this account, be extensible at least in two spatial directions and be able to deform themselves around a catheter, accept objects with differing diameters and finally act as a sealing agent. After the catheter has been withdrawn, the elastomer material can only contract on itself in order to once again effect a tight closure of the opening which was made by said catheter. The vector of this contraction force is, however, mostly directed counter to the necessary force for the closure of the slits. This has led to the situation, in which valves of conventional material can scarcely reach a satisfactory sealed closure with only one diaphragm. On this account, as described above, increasingly complex shaping has been developed for the valves and the diaphragms.

Not only do these designs call for complicated and expensive production processes, but the objects become more prone for debilitating disturbances. In areas of application in sensitive medicinal/surgical usage, disturbances and failures in operation cannot be tolerated.

The purpose of the Invention

Because of the above deficiencies, the present invention has the purpose of making available a failure-free functioning hemostatic valve, of the simplest possible design, and of low cost in its production.

This purpose will be achieved by a hemostatic valve designed in accord with the generic concept of Claim 1.

Further variant embodiments become evident from the subordinate claims.

In the drawings, several embodiment examples are presented and with the help of said drawings, these examples will be fully explained. There is shown in:

Fig. 1 a cross-section through the valve carrying zone of an instrument for the introduction of catheters with a completely installed dilator, wherein, to the right of the centerline L the sealing element is depicted, and to the left of the centerline L, the said sealing element is not shown,

Fig. 2 an enlarged view of the hemostatic valve showing its encompassing housing, wherein, to the left of the centerline L, the dilator is elided, and to the right of the centerline L, an installed dilator is presented,

Fig. 3a a perspective, exploded view of the valve body,

Fig. 3b a perspective view of an additional embodiment of the valve body,

Fig. 3c a perspective view of yet another embodiment of the valve body, and

Fig. 4 a cross-section through a valve in accord with 3b.

Description with help of the drawings

The two-part housing G in Fig. 1, comprises one housing body 1 and a housing top 2. The housing body 1 of the catheter introduction instrument is essentially, as a hollow cylinder with a central opening, which narrows itself from its distal end 12 to its proximal zone 13, and possesses a side connection fitting 11. In the interior of the housing body 1, directly above the entry of the side opening 111 and perpendicular to the longitudinal axis L, is to be found a valve support surface 19. Coacting with a valve clamping surface 28 of the inner surface 22 of the housing top 2, a sealing element 10 is held in form and force fit between said support surface 19 and the valve clamping surface 28. The sealing element 10 subdivides the interior space of the housing G into hollow spaces designated, respectively, as distal cavity 21 and proximal cavity 14. The proximal cavity 14 stands in communication with the central hollow space Z which is formed by an operational sheath 5. The purpose of the sealing element 10 is to prevent the overflow of fluid from the proximal cavity 14 to the distal cavity 21 and to block passage of air in the opposite direction. An inner side wall 15 of the proximal cavity 14 conically tapers itself downward and eases the insertion of elongated objects into the central channel opening Z of the operational sheath 5. This operational sheath 5 is an elongated, flexible tube, which, on its distal end, is closely embraced by a proximal wall 13 of the housing body 1 and force fit thereto. Slipped over the proximal end 13 of the housing body 1 is a conical nozzle 4 of an elastic, stretchable material, the inside diameter of which, in its non-extended condition, is smaller than the outside diameter of the proximal housing wall 13. A retaining ridge 18, which encircles the proximal housing wall 13 penetrates into a corresponding groove 44 of the inside of the nozzle 4, and supports thereby, the force fit retention of the nozzle 4 on the housing body 1. In a proximal direction, the nozzle 4 extends over the housing body 1 and encapsulates with its proximal zone 42 the operational sheath 5. The nozzle 4 possesses a lateral fastening tab 41, which has been provided with a hole 43.

The U-shaped housing cap 2 possesses an inner wall 22 and an outer wall 23. In an extension in the distal direction of the inner housing wall 22, a plurality of radial, resilient securement fingers 24 protrude. Each of these fingers 24, respectively, possesses an inwardly protruding ridge 25 and an upper, contact surface 27, which is perpendicular to the longitudinal axis L. The circumferential, U-shaped in cross section recess, which is formed by the inner 22 and the outer 23 walls of the housing cap 2, is so dimensioned that it can receive the distal end 12 of the housing body 1, when the said cap 2 is set upon the housing body 1. A longitudinally extended dilation tube 31 of the dilator 3 can penetrate only so far into the operational sheath 5, until a detent 34 of a dilator end-piece 33 abuts the detent contact surface 27. When the dilator 3 is fully inserted, the radially disposed holding fingers 24 hold and support a proximal part of the dilator end-piece 33 by their said ridges 25. The assembly of the instrument for introducing catheters is considered to be simple, since all component materials are connected together by snap contact and thus no adhesive operations, nor welding, or screwing is required. Principally the distal end of the operational sheath 5, in a first work-step must be made fast with the housing body 1 by means of adhesive or welding. The other components can naturally be adhesively affixed, or welded with heat or ultra-sonic means.

We now consider the valve sealing unit 10 in the general assembly of the instrument. Annular reinforcement plates 101, 102 and the interposed sealing disk 103 possess an outer diameter D_A designed to fit the inside diameter of distal housing wall 12. These components are mounted upon the valve contact surface 19. When the cap 2 is firmly put in place, these said components are pushed over the distal area of the housing wall 12. Sliding continues until the circumferential retaining ring 26 on the inside of the outer wall 23 snaps into a corresponding circumferential groove 16 on the outside of the distal housing wall. The height of the inner cap wall 22, the position of the circumferential groove 16 and the retaining ring 26 are dimensionally correlated to one another. This dimensioning is such that the said valve clamping surface 28 of the inner cap wall 22, on the now snapped in cap 2 is found at a certain distance in an axial direction from the valve contact surface 19

This distance is equal to or less than the thickness H of the inserted sealing element 10.

The pressure on the two supporting annular plates 101, 102 is transferred to the sealing disk 103. The so compressed sealing disk expands itself laterally and thus activates the gas and liquid impermeability of the sealing element 10 from the housing body 1.

As is presented in the Figs. 3a, 3b and 3c, the sealing element consists of two annular support plates 101, 102 composed of surgical steel or hard plastic with an interposed sealing disk 103, this latter being of soft, elastic foamed plastic. This disk 103 possesses at least two radially running slits 104 which do not reach to the circumference. The slits 104 penetrate through the sealing disk 103, i.e. through its entire thickness. More ideally, three slits would form a Y-shaped slotting, or four slits an x-shaped penetration. This situation is respectively shown in Figs. 3b, 3a. Fig. 3c depicts a further variant of a sealing disk with six radial slits. Naturally, additional embodiments of the invented sealing element 10 are possible with differing numbers of slits or different shapes of slitting.

The diameter D_i of a central penetration opening 105 of the annular plates 101, 102 is greater than the diameter of the largest object to be guided therethrough. The thickness of the annular support plates 101, 102 is about one multiple less than the thickness of the sealing disk 103. Since the distal and the proximal annular support disks 101, 102 must prevent the escape of the sealing disk 103 in the direction of the longitudinal axis L, the size of the central circular opening 105 diameter is limited. This diameter must correspond to the thickness and to the stability of the sealing disk 103. In a preferred embodiment of the invention, the inner diameter D_x of the central penetration opening 105 is 3.6 mm and the thickness of the sealing disk 103 is 2 mm. The said thickness can run, optionally, between 1 and 3 mm. It would be prudent to determine the diameter D_i of the central opening 105 of the annular support plates 101, 102, the dimensioning of the sealing disk 104, as well as the diameter of the operational sheath 5 so that all to conform to defined standard catheter dimensions and diameters.

For this purpose, ideally, the nominal sizes in accord with DIN 13 273 could be used. The corresponding Charriere-number, for instance, can be applied to the nozzle 42. An advantage would be to have individual, well visible components of the instrument for introducing catheters distinguished by corresponding DIN color coding.

The sealing means, in accord with the invention, meets the severe demands as to function by the use of new types of material for the manufacture of the sealing disk 103. Soft, elastic, foamed plastic with a density of 300 to 600 g/l, preferably 450 g/l possess the required material characteristics. In order to maintain the microporous material, which has pore sizes between 10 to 1000 µm, in a state which evidences good compressibility and impregnation, the material was advantageously open-porous. It is also possible that it can be selected from closed porous substances.

Upon the insertion, withdrawal, and movement of the catheter, the sealing disk 103 is only slightly moved in an axial direction, since the two annular support plates suppress this movement.

If an object is slipped through the slit 104 of the sealing disk 103, then the lips formed by the slits 104 are pressed laterally from the central axis toward the outside, and simultaneously compressed. This lateral compression, instead of an axial displacement is supported by the following factors:

- the foamed material is easily compressed, but difficult to stretch,
- the friction between the catheter and the sealing disk 103 is reduced by a lubricant, for instance, silicone or a paraffin oil, and
- the thickness of the sealing disk 103 is greater than the radius of the central opening 105 of the supporting annular plates 101, 102 and thus, greater than the radius of the largest object to be passed through the instrument.

The surface of the catheter, which stands in direct contact with the sealing disk 103 remains relatively constant, even with a to-and-fro movement of the catheter.

This, and the additional use of a lubricant to ease sliding, such as, for instance, silicone or a paraffin oil, hold the forces which arise from movement of the catheter at a low and constant level. Finally, the latter is decisive for sensory control of the catheter movement by the surgeon and thus decisive for the acceptance of the product by the user.

If the catheter be withdrawn, then the compressed material retracts into its original position. The soft, elastic foamed plastic possesses sufficient tensile strength in order to keep the slits 104 non-leaking under sufficient physiological pressure relationships upon catheter removal and thus to act as a gas tight barrier between the proximal cavity 14 and the distal cavity 21.

Claims

Claimed is:

1. An instrument for the introduction of a catheter with a hemostatic valve for the insertion of a catheter into a blood vessel, wherein the hemostatic valve is enclosed in a two-part housing and wherein, between the two housing parts of the said instrument for introduction is provided and retained by shape and force at least one sealing element (10) for the sealed penetration of an elongated component, therein characterized, in that the sealing element (10) is comprised of at least one sealing disk (103) of a soft, elastic, foamed plastic material.

2. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the sealing element (10) is composed of at least the sealing disk (103) and respectively one thereto corresponding distal and proximal located annular support disks (101, 102).

3. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the sealing disk (103) possesses at least two radially disposed slits (104) which do not extend to the circumference.

4. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the sealing disk (103) is composed of a microporous material with pore sizes of from 10 to 1000 µm.

5. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the material of the sealing disk (103) exhibits a density of 300 to 600 g/l, preferably 450 g/l.

6. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the material of the sealing disk (103) is preferably open porous.

7. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the sealing disk (103) is impregnated with silicone or with paraffin oil.

8. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the distal and the proximal annular support plates (101, 102) possess each one central opening (105), the diameter D_1 of which is greater than the diameter of that penetrating object which is the greatest in diameter of the elongated components which are to penetrate the said instrument.

9. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the two annular supporting plates (101, 102) are composed of surgical steel or hard plastic.

10. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the sealing disk (103) possesses a thickness of from 1 to 3 mm, preferably 2 mm.

[This completes the text with the original claims]

Changed Claims

[Alteration by the International Office on June 12, 1998
of the originally submitted Claims 1 to 10
to new Claims 1 to 7]

Claims

Claimed is:

1. An instrument for the introduction of a catheter with a hemostatic valve for the insertion of a catheter into a blood vessel, wherein the hemostatic valve is enclosed in a two-part housing and wherein, between the two housing parts of the said instrument for introduction is provided and retained by shape and force at least one sealing element (10) for the sealed penetration of an elongated component, wherein the sealing element (10) consists of at least one, open pore sealing disk (103) impregnated with silicon or paraffin oil and made of a soft, elastic foamed plastic material, therein characterized, in that the sealing element (10) consists of at least the sealing disk (103) and respectively a distal and proximal thereto corresponding annular support plate (101, 102).

2. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the sealing disk (103) possesses at least two radially extending slits (104) which do not extend to the circumference.

3. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the sealing disk (103) is composed of a microporous material with a pore size of from 10 to 1000 µm.

4. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the material of the sealing disk (103) exhibits a density of from 300 to 600 g/l, preferably 450 g/l.

5. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the distal and the proximal annular support plates (101, 102) possess each one central opening (105), the diameter D_1 of which is greater than the diameter of that penetrating object which is the greatest in diameter of the elongated components which are to penetrate the said instrument.

6. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the two annular support plates (101, 102) consist of surgical steel or hard plastic.

7. An instrument for the introduction of a catheter in accord with Claim 1, therein characterized, in that the sealing disk (103) possesses an annular width of 1 to 3 mm, preferentially, 2 mm.

[This completes the assigned translation]

INTERNATIONAL SEARCH REPORT

Int Sional Application No
PCT/CH 98/00001

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M39/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	US 5 207 656 A (KRANYS) 4 May 1993 see column 3, line 22 - column 4, line 42; figures 1-5	1,3,4,6 2,8,9 7
X	US 5 098 393 A (AMPLATZ ET AL) 24 March 1992 see column 2, line 35 - line 45 see column 3, line 30 - column 4, line 2; figure 2	1,7,10
X	EP 0 198 962 A (TERUMO CORP) 29 October 1986 cited in the application see page 2, line 5 - line 37; figures 1,2 see page 6, line 20 - page 7, line 6; claims 1,2; figures 3,4	1,3

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
15 April 1998	27/04/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Levert, C

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH 98/00001

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 966 586 A (VAILLANCOURT) 30 October 1990 see column 7, line 29 - column 8, line 27; figures 3,4	2,8,9

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

ALREADY IN ENG

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CH 98/00001

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

ADDITIONAL MATTER

1. Claims: 1,3,4,5,6,7,10
Instrument for introducing catheters with sealing washer

2. Claims: 1,2,8,9
Instrument for introducing catheters with supporting ring

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CH 98/00001

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5207656 A	04-05-93	NONE	
US 5098393 A	24-03-92	NONE	
EP 0198962 A	29-10-86	JP 61154679 A CA 1254476 A US 4673393 A	14-07-86 23-05-89 16-06-87
US 4966586 A	30-10-90	NONE	

ALREADY IN ENGLISH

English International Search Report			Application No. PCT/CH 98/00001
Patent document cited in search report	**Publication Date**	**Patent Family Members**	**Publication Date**
US 5207656 A	May 4, 1993	NONE	
US 5098393 A	March 24, 1992	NONE	
EP 0198962 A	Oct. 29, 1986	JP 61154679 A CA 1254476 A US 4673393 A	July 14, 1986 May 23, 1989 June 16, 1987
US 4966586 A	Oct. 30, 1990	NONE	

FIG.1

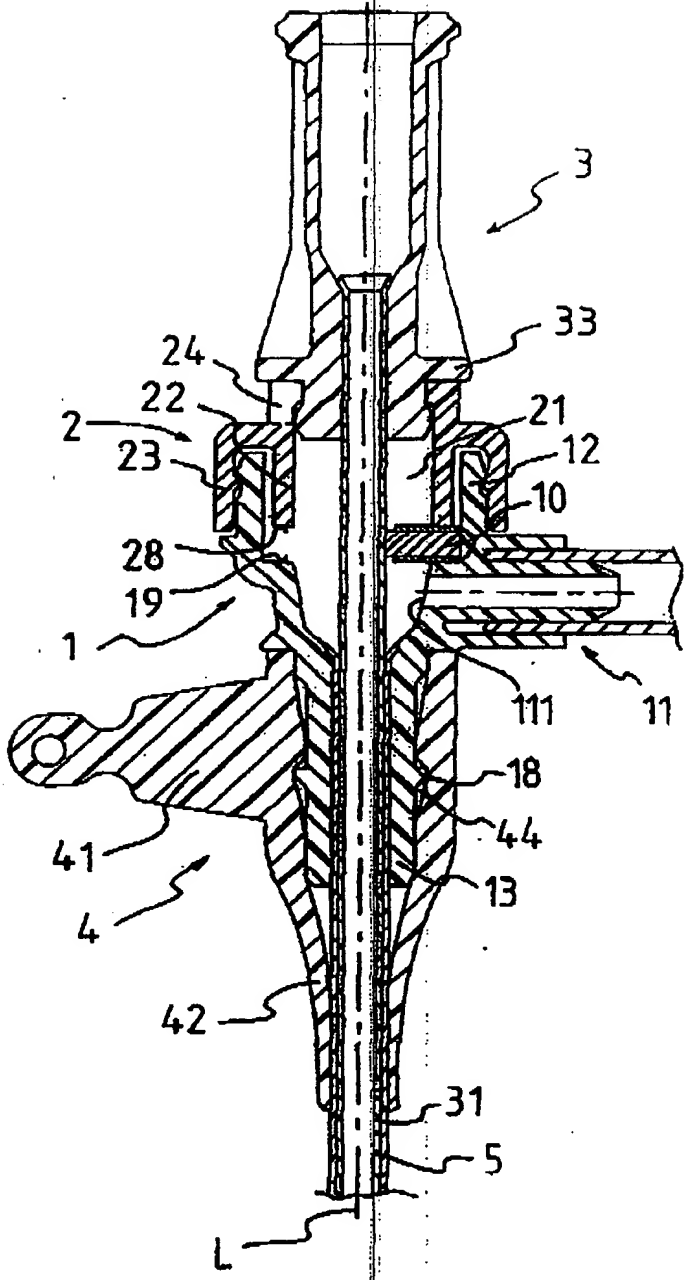

FIG. 2

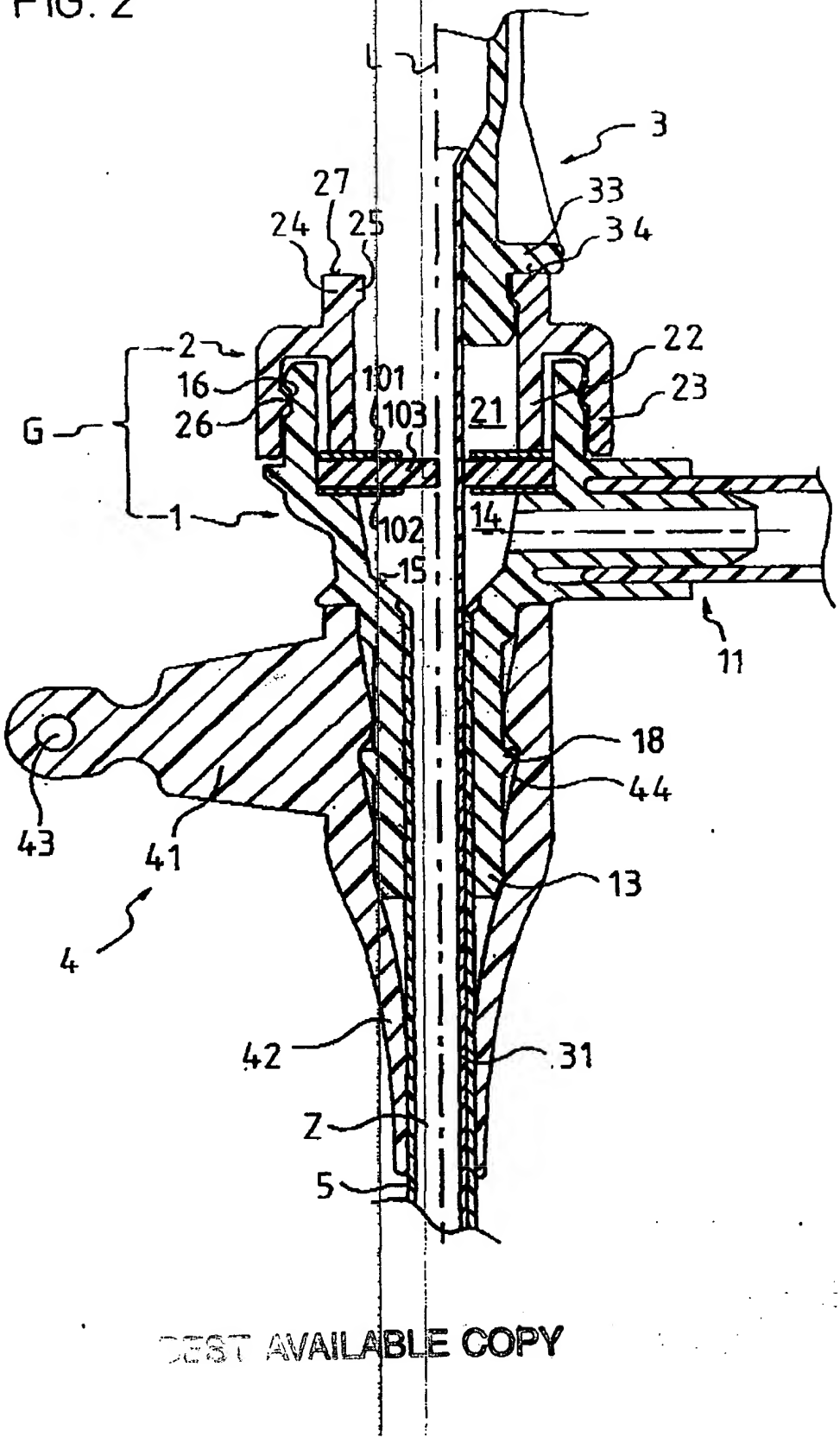

FIG. 3a

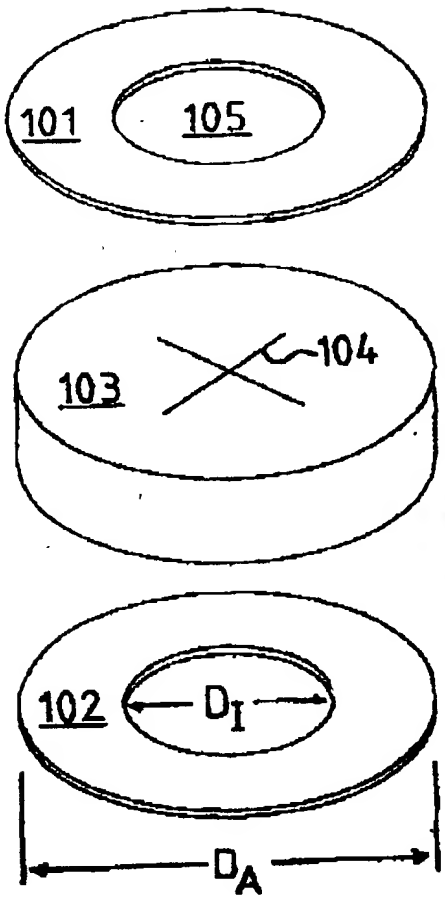

FIG. 3b

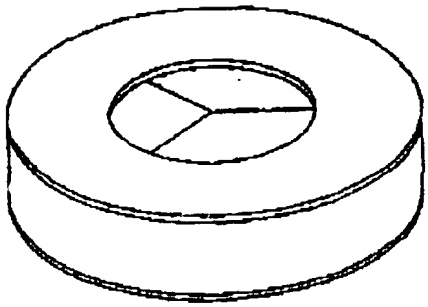

FIG. 3c

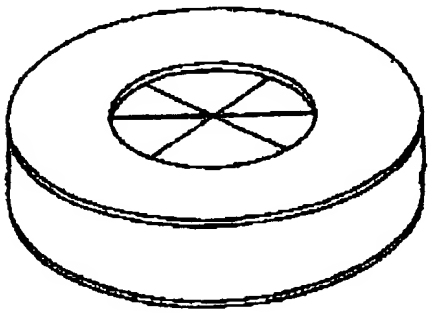

FIG. 4